

REMARKS

Claims 32-43, 63-71, and 73-78 are currently pending in the present application. Claims 32-43, 63-71, and 73-78 are rejected. The title of the invention has been amended as per the Examiner's suggestion. Claim 63 has been amended. Support for this amendment can be found throughout the specification, for example, at paragraph 37. All claim amendments are made without prejudice and do not represent an acquiescence in any ground of rejection.

The present invention is directed to biocompatible bone graft materials comprising polymers (e.g., collagen) and calcium phosphate, wherein the materials have interconnected macro-, meso-, and microporosity. The present invention is also directed to bone grafts for long bone reinforcement comprising biocompatible, resorbable sleeves of a polymer and beta-tricalcium phosphate, wherein the grafts have interconnected macro-, meso-, and microporosity. The present invention is further directed to grafts comprising a homogenous composite of polymer, beta-tricalcium phosphate, and a mesh, wherein the grafts have interconnected macro-, meso-, and microporosity and are shaped to conform generally to a mammalian anatomical tissue structure.

Objection to the Specification

The title has been amended as suggested by the examiner to an entirely equivalent title.

Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 71 and 73-78 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Action, it is allegedly unclear how a composite of polymer and β -tricalcium phosphate is to be homogenous as the term "homogeneous" implies "a single component, not a composite of two or more."

The Applicants respectfully disagree. The Applicants invite the Examiner to look to page 9, para. 36 wherein the term "homogeneous" has been defined. As per the Specification, "homogenous means that the ratio of components *within the mixture* is the same throughout." (emphasis supplied). In light of the definition supplied in the

Specification, and the knowledge of one of skill in the art, the Applicants submit that claims 71 and 73-78 are not indefinite and that they particularly point out and distinctly claim the invention. Applicants respectfully request that the rejection under 35 U.S.C. § 112 be withdrawn.

Claim Rejection under 35 U.S.C. § 102

Claim 63 stands rejected under 35 U.S.C. 102(b) as allegedly anticipated by Sapiesko et al (U.S. Pat. No. 6,383,519) assigned to the present assignee. Sapiesko does not teach the use of collagen, as presently claimed. As Sapiesko does not teach all of the elements, features, or limitations of the present invention, Applicants respectfully request that the rejection under 35 U.S.C. 102(b) as allegedly anticipated by Sapiesko et al. be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 32-40, 63, 67-70, and 74-78 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Piez et al (U.S. Pat. No. 4,795,467), in light of Bachard. It is believed that the Examiner used the Bachard document merely to provide a definition of the components of SYNTHOGRAFT. As such, only the Piez patent will be discussed in this response.

The Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner must meet three criteria: (1) there must be some suggestion of motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. M.P.E.P. § 2143. "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." M.P.E.P § 2143. As the Examiner has failed to meet these criteria, the Applicants respectfully request that the rejection be withdrawn.

The Examiner has acknowledged that Piez does not teach bone grafts having interconnected macro-, meso-, or microporosity and the Applicants agree. In a prior communication, the Applicants erroneously stated that Piez teaches a material having a

preferred pore size range of 100-2000 μm , citing to column 3, lines 10-11 of Piez. Upon further consideration, however, it is clear that Piez does not teach materials having preferred pore size ranges. According to Piez, “[T]he mineral is generally and preferably of non-biological origin and is supplied as powder of appropriate mesh. Preferred *particle sizes* are in the range of 100-2000 μ .” (col.3, lines 8-11, emphasis supplied). “Particle sizes” are not considered to be equivalent to “pore sizes” to one of skill in the art. The Applicants apologize for any confusion this may have caused the Examiner.

Piez teaches that the collagen gel content of composites prepared according to the method of Piez are limited to the “void space” between the HA particles and that using 20-40 mesh HA will yield a ratio of 25:75 collagen to HA by weight. (col. 5, lines 63-67). The Examiner states that the “size range of the pores is a result effective variable” and that it would have been obvious to use particles with varied mesh sizes in order to achieve macro-, meso-, and microporosity in the bone graft of Piez. The Applicants respectfully disagree.

There is no suggestion or teaching in Piez that “void spaces” are the equivalent of the interconnected porosity described in the present invention. Moreover, there is no suggestion in Piez, or in any other art cited by the Examiner, to combine a *variety* of mineral particle mesh sizes to create a material having a variety of differently sized “void spaces.” Combining a variety of mineral particle mesh sizes is not a result effective variable because the experimentation required to combine a variety of mesh sizes “would not have come from within the teachings of the art.” *See In re Waymouth*, 182 U.S.P.Q. 290 (C.C.P.A. 1974) (“We cannot agree with the Board that appellants’ claimed ratio was the result of obvious experimentation, since, in our judgment, any such experimentation would not have come from within the teachings of the art.”). At most, Piez suggests that a uniform increase or decrease in the mesh size of the particles would result in a uniform change in the size of the “void spaces.” Piez does not teach or suggest the employment of a variety of mesh sizes, therefore, the Examiner has not established a *prima facie* case of obviousness.

The Examiner is required to show reasons that one of skill in the art, when confronted with the same problems as the inventors and with no knowledge of the claimed invention, would modify Piez to produce the claimed invention. *See In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). The Examiner has failed to provide reasons why one of skill in the art would have modified Piez as the Examiner suggests, in order to produce the claimed

invention. Mere conclusory statements that it would have been obvious to one of skill in the art to modify Piez are insufficient to sustain the Examiner's burden of establishing a *prima facie* case of obviousness. Indeed, without citation to reasons why modification would have been obvious, the Examiner has impermissibly relied on hindsight in formulating the obviousness rejection. As the Examiner has failed to establish a *prima facie* case of obviousness, the Applicants respectfully request that the rejection of claims 32-40, 63, 67-70, and 74-78 under 35 U.S.C. § 103(a) as allegedly unpatentable over Piez, in light of Bachard, be withdrawn.

Claims 41-43, 63-66, 71 and 73 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Piez et al. (U.S. Pat. No. 4,795,467), in light of Bachand, in view of Koblish et al. (U.S. Pat. No. 6,458,162), and in further view of Lin et al. (U.S. Pat. No. 6,458,162) and Sanders et al. (U.S. Pat. No. 5,290,289). In light of the comments made above, this rejection is moot. Piez does not teach a bone graft material having interconnected macro-, meso-, or microporosity, nor is there any suggestion or motivation in Piez itself or in the knowledge of one of skill in the art, to modify Piez to produce a bone graft material having interconnected macro-, meso-, or microporosity. As such, the combination of references cited by the Examiner can not teach or suggest all the claim limitations of the present invention. The Applicants respectfully request that this rejection be withdrawn.

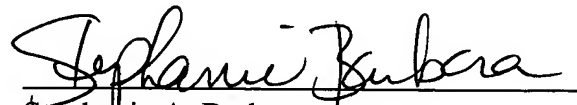
Claim 70 stands rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Sapienko et al. (U.S. Pat. No. 6,383,519). In light of the amendment to claim 63, upon which claim 70 depends, this rejection is moot. The Applicants respectfully request that this rejection be withdrawn.

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**PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

The Applicants respectfully submit that the foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicants submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 215-564-8918.

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Stephanie A. Barbosa
Registration No. 51,430

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439